DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Gonal-F
Docket No.: 98E-0488

APR 20 1999

The Honorable Q. Todd Dickinson
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

Dear Commissioner Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 5,156,957, filed by Genzyme Corporation, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Gonal-F, the human drug product claimed by the patent.

The total length of the regulatory review period for Gonal-F is 2,044 days. Of this time, 569 days occurred during the testing phase and 1,475 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: February 26, 1992.

   FDA has verified the applicant's claim that the date the Investigational New Drug application became effective was on February 26, 1992

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: September 16, 1993.

   FDA has verified the applicant's claim that the new drug application (NDA) for Gonal-F (NDA 20-378) was initially submitted on September 16, 1993.

3. The date the application was approved: September 29, 1997.

   FDA has verified the applicant's claim that NDA 20-378 was approved on September 29, 1997.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis

Thomas J. McGinnis, R.Ph.
Deputy Associate Commissioner
for Health Affairs

cc: Roger L. Browdy
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